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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/530,260	07/12/2000	KENGO AKIMOTO	001560-381	7267
7590	07/25/2002			
RONALD L GRUDZIECKI BURNS DOANE SWECKER & MATHIS PO BOX 1404 ALEXANDRIA, VA 22313-1404			EXAMINER	
			MARX, IRENE	
		ART UNIT	PAPER NUMBER	
		1651	13	
DATE MAILED: 07/25/2002				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No. 09/530,260	Applicant(s) Akimoto et al.
Examiner Irene Marx	Art Unit 1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on May 29, 2002

2a) This action is FINAL. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-37 is/are pending in the application.

4a) Of the above, claim(s) 1-10, 13-16, and 23-26 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 11, 12, 17-22, and 27-37 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are a) accepted or b) objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. _____.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) The translation of the foreign language provisional application has been received.

15) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892)

4) Interview Summary (PTO-413) Paper No(s). _____

2) Notice of Draftsperson's Patent Drawing Review (PTO-948)

5) Notice of Informal Patent Application (PTO-152)

3) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 10

6) Other:

The application should be reviewed for errors. Error occurs, for example, in the spelling of “*Penicullium*” in claim 17, and in the spelling of “arachdonic” in claim 27.

The amendment filed 5/29/02 is acknowledged. Claims 11-12, 17-22, and 27-37 are being considered on the merits. Claims 1, 2, 4-8, 10, 12-16 and 18 are withdrawn from consideration. Applicants indicate in the remarks that claims 21 and 22 are cancelled, however no particular instructions are provided in this regard.

The clean and marked up version of claim 11 are not the same. The clean version is being examined.

For claim 17, no clean version is provided. The claim at page 2 includes brackets. Correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 11-12, 17-22, and 27-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 11 and 21 appear to be substantial duplicates. Claims 12 and 22 appear to be substantial duplicates. Claim 21 is confusing in the recitation of “of arachidonic acid in fat”. Antecedent basis for “fat” is unclear.

Claims 11-12, 17-22 and 27-33 are confusing in that it is not specified whether the weight percent is dry or wet weight. No new matter may be added.

Claims 34-37 are confusing in the recitation “subgenus *Mortierella*”. The nature of this taxonomic group is not clear on this record.

Applicant’s arguments have been fully considered but they are not deemed to be persuasive.

The basis for applicant’s allegation that one of ordinary skill in the art would know whether dry or wet weight is intended is not set forth. The arguments by counsel in this regard

have not been substantiated with appropriate evidence. It is well settled that arguments by counsel do not constitute evidence. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. *In re Van Guens*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). In addition, the limitations of the claims must be clear and unambiguous to one of ordinary skill in the art. It is noted that there is no definition of "weight" to indicate whether wet or dry is intended.

Therefore the rejection is deemed proper and it is adhered to.

Claim Rejections - 35 USC § 112

Claims 36 and 37 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ a novel strain of *M. alpina* to obtain a specific product. The written description of that strain and the method of isolating is insufficiently reproducible. Therefore, a deposit for patent purposes is required. The specification discloses at page 12 that was deposited under Budapest Treaty conditions at the National Institute of Biosciences and Human Technology of the Agency of Industrial Science and Technology.

For compliance with the rule, it must be averred that deposited material has been accepted for deposit under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the purpose of Patent Procedure (e.g. see 961 OG 21, 1977) and that all restrictions on the availability to the public of the material so deposited will be irrevocably removed upon the granting of a patent. MPEP 2403.

Additionally, the deposit must be referred to in the body of the specification and be identified by deposit (accession) number, date of deposit, name and address of the depository and the complete taxonomic description.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 11-12, 17-22 and 27-37 are/remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Totani *et al.*.

The claims are drawn to a microbial lipid containing arachidonic acid at levels higher than 50% or 70%..

The cited reference discloses a microbial lipid containing arachidonic acid which appears to be identical to the presently claimed microbial lipid containing arachidonic acid since the lipid from *Mortierella* contains 90% arachidonic acid (See, e.g., page 59, paragraph 2). The referenced microbial lipid containing arachidonic acid appears to be identical to the presently claimed composition and is considered to anticipate the claimed composition since it is of the same class as that of the microbial lipid claimed, it shares substantially the same origin and contains substantially the same amount of arachidonic acid as claimed. Consequently, the claimed composition appears to be anticipated by the reference.

In the alternative, even if the claimed microbial lipid is not identical to the referenced microbial lipid with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microbial lipid is likely to inherently possess the same characteristics of the claimed microbial lipid particularly in view of the similar characteristics which they have been shown to share. Thus the claimed microbial lipid would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 11-12, 17-22 and 27-37 are/remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Li *et al.*.

The claims are drawn to a microbial lipid containing arachidonic acid at levels higher than 50% or 70%..

The cited reference discloses a microbial lipid containing arachidonic acid which appears to be identical to the presently claimed microbial lipid containing arachidonic acid enzyme. since the lipid from *Mortierella* contains 72.5% arachidonic acid (See, e.g., page 138, first full paragraph and Table 6).

The referenced microbial lipid containing arachidonic acid appears to be identical to the presently claimed composition and is considered to anticipate the claimed composition since it is of the same class as that of the microbial lipid claimed, it shares substantially the same origin and contains substantially the same amount of arachidonic acid as claimed. Consequently, the claimed composition appears to be anticipated by the reference.

In the alternative, even if the claimed microbial lipid is not identical to the referenced microbial lipid with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced microbial lipid is likely to inherently possess the same characteristics of the claimed microbial lipid particularly in view of the similar characteristics which they have been shown to share.

Thus the claimed microbial lipid would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Applicant's arguments have been fully considered but they are not deemed to be persuasive.

Contrary to applicant's argument that Totani teaches a "mixture of fatty acids" rather than lipid containing arachidonic acid, it is noted that Totani discloses at page 52, paragraph 2, a fungal lipid containing up to 80% arachidonic acid and indicates at page 56, last paragraph that arachidonic acid comprised 71.2% of the total fatty acid content of the cells. One of ordinary skill in the art would reasonably have concluded that the cells contained lipids and not free fatty acids, as now argued.

With respect to Li *et al.*, it is noted that Li states that the "recovered oil contained arachidonic acid 72.5% w/w" at page 138, paragraph 4. Since oils are lipid, this statement is not directed to a composition containing only fatty acids.

In response to arguments directed to the process steps directed to the use of a mutant having decreased ω 3 desaturase, it is noted that "The patentability of a product does not depend upon its method of production. If the product in [a] product-by-process claim is the same as or obvious from a product of the prior art, [then] the claim is unpatentable even though the prior [art] product was made by a different process." *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted). Once the examiner provides a rationale tending to show that the claimed product appears to be the same or similar to that of the prior art, although produced by a different process, the burden shifts to applicant to come forward with evidence establishing an unobvious difference between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289, 292 (Fed. Cir. 1983).

Furthermore, the composition is claimed as a product-by-process. Since the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is

required to make out a case of *prima facie* anticipation/obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

It is also of interest to note with respect to the argued process limitations in the product claims, that at least claim 27 and claims dependent thereon are directed to a lipid "obtainable" by culturing a broad class of mutants and ultimately, in dependent claims, a lipid "obtainable" from a specific strains. However, the claim is at least ambiguous regarding other sources of the lipid intended. It is submitted that the fact that a lipid is "obtainable" from a specific strain does not confer a patentable distinction on the lipid claimed.

Therefore the rejections are deemed proper and are adhered to.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.


Irene Marx
Primary Examiner
Art Unit 1651

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.

Irene Marx
Irene Marx
Primary Examiner
Art Unit 1651